

**Remarks**

To further prosecution of the present application, Applicant has amended herein Claims 19, 37, 40, and 41, and has cancelled herein Claim 38. Claim amendments have antecedent basis and do not add subject matter. Claims 19-20, 22-25, 27-37, and 39-41 are currently pending with Claims 19 and 37 in independent form.

Applicant respectfully requests reconsideration.

**Rejection of Claims 19, 20, 23-25, and 27-39 under 35 U.S.C. § 103(a)**

Claims 19, 20, 23-25, and 27-39 are rejected under § 103(a) as being unpatentable over U.S. 4,559,934 to Philipp ("Philipp") in view of U.S. 6,592,539 to Einarsson et al. ("Einarsson"). Applicant respectfully traverses the Examiner's rejection of the claims under § 103(a) as being unpatentable over Philipp in view of Einarsson.

Independent Claim 19 has been amended herein and is directed to:

19. An ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising:
- a compression stocking formed of contiguous first and second tubular members, said second tubular member being set at an angle to the first tubular member to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of the patient; and
  - a flexible rib of silicone elastomer, at least a portion of an external surface of a defined region of the compression stocking; said defined region being substantially aligned with at least a portion of the dorsum of the patient's foot when said orthosis is in use; being impregnated with said silicone rib to bond said rib to said region of the compression stocking, such that said rib overlies at least a portion of the dorsum of the patient's foot when said orthosis is in use and has a resilience that is appropriate for resisting the particular degree of plantarflexion experienced by the patient.

In the Action, the Examiner contends that Philipp discloses the limitations of Claim 19 with the exception Philipp fails to disclose the rib is composed of a silicone elastomer, and fails to disclose the rib is bonded to a region of the compression stocking. (See Office Action mailed 10/2/2009, page 3). The Examiner cites Einarsson as disclosing an orthotic tubular sleeve including a portion coated with silicone elastomer bonded to the fabric material of the sleeve (Col. 1, line 45-50) that is cured (Col. 4, lines 25-33). The Examiner, therefore, concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to integrate the rib of the Philipp device by the known technique of bonding as taught by Einarsson

in order to allow an alternative form of permanent attachment of the rib to the compression stocking.

Applicant submits that the cited combination of the teachings of Einarsson with Philipp does not render the claimed invention specified in Claim 19 obvious. More specifically, Applicant submits that Einarsson does not cure the deficiencies of Philipp that the Examiner identifies with respect to the rib bonded to a region of the compression stocking. In addition, Applicant submits that the cited combination of Philipp in view of Einarsson does not achieve the claimed invention specified in Claim 19.

The Examiner indicates that Einarsson discloses:

The entire inner surface of the sleeve is coated with a discrete layer of silicone elastomer that is firmly bonded to the fabric material constituting the sleeve. The silicone elastomer layer is thick enough and soft enough to be very comfortable to the user and to provide an airtight seal between the sleeve and the skin. (Col. 1, lines 45-50).

After the sleeve 20 has been fabricated in the manner described above by joining sections A, B, and C, the inside surface of the entire sleeve is coated with a cured silicone elastomer (40) material that is firmly bonded as a discrete layer with the interior surface of the fabric sections 10, 12, and 14. The silicone elastomer material on the inside surface of the sleeve 20 is shown in FIGS. 5 and 6. (Col. 4, lines 25-33).

In contrast to Einarsson, Claim 19 specifies with respect to the flexible rib of silicone elastomer: *at least a portion of an external surface of a defined region of the compression stocking; said defined region being substantially aligned with at least a portion of the dorsum of the patient's foot when said orthosis is in use; being impregnated with said silicone rib to bond said rib to said defined region of the compression stocking, such that said rib overlies at least a portion of the dorsum of the patient's foot when said orthosis is in use.*

The rib of silicone elastomer specified in Claim 19 is structurally different from the discrete layer of silicone elastomer coated on the entire inner surface of the sleeve of Einarsson. The rib of Claim 19 does not cover an entire surface or an inner surface of the compression stocking, as Einarsson discloses. Rather, Claim 19 recites at least a portion of an external surface of a defined region of the compression stocking is impregnated with the rib to bond the rib to the defined region. The defined region Claim 19 specifies is substantially aligned with at

least a portion of the dorsum of the patient's foot when said orthosis is in use, which is not the entire inner surface of the compression stocking.

Moreover, Einarsson discloses that the entire inner surface of the sleeve is coated with a layer of silicone elastomer that is thick enough and soft enough to be comfortable to the user. In contrast, Claim 19 specifies that the rib of silicone elastomer bonds to a portion of an external surface of the defined region, such that the rib overlies at least a portion of the dorsum of the patient's foot when the orthosis is in use. The location of the rib of Claim 19 along the compression stocking relates to the rib's resistance to plantarflexion experienced by the patient, while the location of the layer of silicone elastomer of Einarsson along the entire inner surface of the sleeve relates to the user's comfort and the airtight seal between the user's skin and the sleeve. Therefore, the structures and positions of the layer of silicone elastomer of Einarsson and the rib of silicone elastomer specified in Claim 1 relative to their respective sleeve and compression stocking are entirely different.

Therefore, Applicant submits that Einarsson does not cure the deficiencies of Philipp with respect to the flexible rib of silicone elastomer specified in Claim 19 as the Examiner contends. Applicant further submits that the suggested combination of the teachings of Einarsson with the device of Philipp to modify the rib of silicone elastomer of Claim 19 clearly does not achieve the combination of limitations of the invention recited in Claim 19.

Thus, Applicant submits that Claim 19 patentably distinguishes Philipp and Einarsson, alone and in the cited combination. Accordingly, Applicant requests withdrawal of the rejection of Claim 19 under § 103(a) as being unpatentable over Philipp in view of Einarsson.

Claims 20, 23-25, 27-36, and 40 depend from Claim 19 and patentably distinguish Philipp and Einarsson, alone or in combination, for at least the reasons given above with respect to Claim 19. Applicant, therefore, requests withdrawal of the rejection of Claims 20, 23-25 and 27-36, and 40 under § 103(a) as being unpatentable over the cited combination of references.

With respect to the independent Claim 37, Claim 37 has been amended herein and is directed to:

37. A method of manufacturing an orthosis for resisting plantarflexion of patient's foot, the method comprising the steps of:

- providing a compression stocking formed of contiguous first and second tubular members set at an angle to one another to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient;

- mounting the compression stocking on a foot-shaped anvil;

- preparing a silicone elastomer having a resilience which is appropriate for resisting the particular degree of plantarflexion experienced by the patient;

- applying the silicone elastomer directly to at least a portion of an external surface of a defined region of the compression stocking, said defined region being substantially aligned with at least a portion of the dorsum of the patient's foot when the orthosis is in use, such that, the silicone elastomer impregnates and bonds to the defined region of the compression stocking and forms a rib that will, in use, overlie the dorsum of the patient's foot;

- curing the silicone elastomer to form a bond between the rib and the compression stocking; and

- removing the compression stocking from the anvil.

Applicant submits that the cited combination of the teachings of Einarsson with Philipp does not render the method specified in Claim 37 obvious. Applicant submits that Einarsson does not cure the deficiencies of Philipp with respect to bonding the rib to a region of the compression stocking. Applicant also submits that the cited combination of Philipp in view of Einarsson does not achieve the limitations of the method specified in Claim 37.

In contrast to Einarsson, Claim 37 specifies: *applying the silicone elastomer directly to at least a portion of the external surface of a defined region of the compression stocking, said defined region substantially aligned with at least a portion of the dorsum of the patient's foot when the orthosis is in use, such that, the silicone elastomer impregnates and bonds to the defined region of the compression stocking and forms a rib that will, in use, overlie the dorsum of the patient's foot.*

Einarsson discloses coating and bonding a discrete layer of silicone elastomer to the entire inner surface of the sleeve. Such a process is in direct contrast to Claim 37 that specifies applying the silicone elastomer directly to at least a portion of the external surface of a defined region of the compression stocking, such that, the silicone elastomer impregnates and bonds to the defined region and forms a rib that will, in use, overlie the dorsum of the patient's foot.

Claim 37 further specifies that the defined region be substantially aligned with at least a portion of the dorsum of the patient's foot when the orthosis is in use.

The methods of Einarsson and Claim 37 clearly require different process limitations with respect to coating/applying and bonding the silicone elastomer that result in different elastomer structures. In contrast to Einarsson, Claim 37 specifies applying silicone elastomer to at least a portion of the defined region's external surface such that the elastomer impregnates and bonds to the defined region and forms a rib. Einarsson coats a discrete layer of elastomer along an entire inner surface of the sleeve to form an inner layer, which is different structurally and functionally.

Applicant, therefore, submits that methods of coating and bonding a discrete layer of silicone elastomer along an entire inner surface of a sleeve that Einarsson discloses does not cure the deficiencies of Philipp, as the Examiner contends, with respect bonding and forming the flexible rib of silicone according to the method of Claim 37. Applicant further submits that the suggested combination of the teachings of Einarsson with the device of Philipp to modify bonding silicone elastomer and forming the rib on the compression stocking does not achieve the combined limitations of the method of Claim 37.

Thus, Applicant submits that Claim 37 patentably distinguishes Philipp and Einarsson, alone and in the cited combination. Accordingly, Applicant requests withdrawal of the rejection of Claim 37 under § 103(a) as being unpatentable over Philipp in view of Einarsson.

Claim 41 depends from Claim 37 and patentably distinguishes Philipp and Einarsson, alone or in combination, for at least the reasons given above with respect to Claim 37. Applicant, therefore, requests withdrawal of the rejection of Claims 41 under § 103(a) as being unpatentable over the cited combination of references.

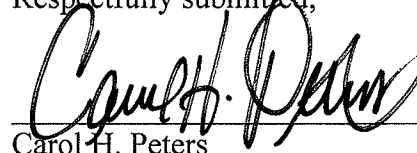
#### Rejection of Claim 22 under 35 U.S.C. § 103(a)

Claims 22 is rejected under § 103(a) as being unpatentable over Philipp in view of Einarsson and further in view of U.S. 4,559,934 to Gardon-Mollard et al. (Gardon-Mollard). Applicant respectfully traverses the Examiner's rejection of Claim 22.

Claim 22 depends from Claim 19 and patentably distinguishes Philipp, Einarsson, and Gardon-Mollard for at least the reasons given above with respect to Claim 19. Therefore, the rejection of Claim 22 should be withdrawn.

Based on the foregoing amendments and discussion, Applicant submits the present application is in condition for allowance, and such action is earnestly solicited. Should the Examiner have any questions concerning this response, he is invited to telephone the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Carol H. Peters", written over a horizontal line.

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